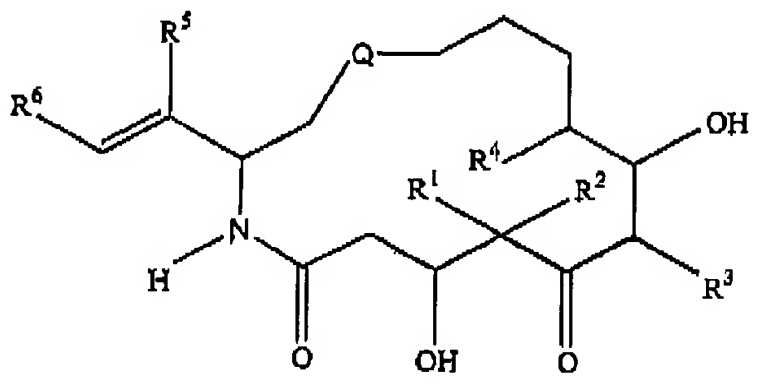
IN THE CLAIMS:

The following is a complete listing of all claims:

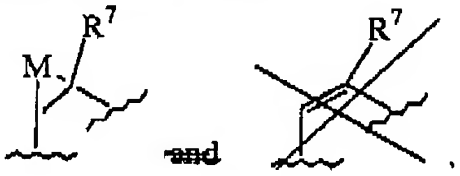
1 (Amended herein). A process for formulating, for parenteral administration, an epothilone analog represented by formula I:



I

wherein:

Q is ~~selected from the group consisting of~~:



~~and~~ ;

M is ~~selected from the group consisting of~~ oxygen, ~~sulfur, NR^8, and CR^9R^{10}~~;

each R^1, R^2, R^3, R^4, R^5, and R^7 ~~R^{11}, R^{12}, R^{13}, R^{14} and R^{15}~~ is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R^1 and R^2 are alkyl, they can be joined to form cycloalkyl;

R^6 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocyclo and substituted heterocyclo;

~~R^8 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, $R^{11}C=O$, $R^{12}OC=O$ and $R^{13}SO_2$; and~~

~~each R^9 and R^{10} is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocyclo, hydroxy, $R^{14}C=O$, and $R^{15}OC=O$;~~

and any salts, solvates, or hydrates thereof, comprising the following steps:

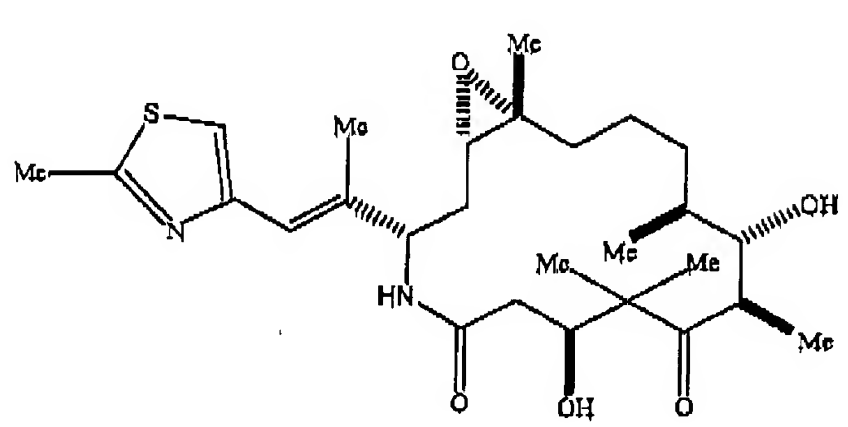
a) dissolving said epothilone analog in a mixture of at least about 50% by volume tertiary-butanol in water to form a solution;

b) performing primary drying of said solution at a temperature of from about -10°C to about -40°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours to form a primary lyophilized product; and

c) performing secondary drying of the ~~resultant~~ primary lyophilized product at a temperature of from about 10 °C to about 30°C under vacuum of from about 50 millitorr to about 300 millitorr for from 24 hours to about 96 hours to provide a lyophilized product of the epothilone analog~~; and~~

~~d) packaging said lyophilized product in a first vial and packaging in a second vial a sufficient quantity of an equal mixture by volume of a suitable nonionic surfactant and anhydrous ethanol to effect solution thereof.~~

2 (amended herein). The process of claim 1 wherein said epothilone analog is represented by formula II:



II

3 (amended herein). The process of claim 1 wherein ~~in~~ step a) comprises first, wetting said epothilone analog ~~is first wetted~~ with a mixture of at least about 60% tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, ~~is added thereto~~ so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said epothilone analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water~~, and said step a) is carried out under protection from light~~.

4 (amended herein). The process of claim 2 wherein ~~in~~ step a) comprises first, wetting said epothilone analog ~~is first wetted~~ with a mixture of at least about 60% tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, ~~is added thereto~~ so that the resulting solution contains from about 2 mg/mL to about 30 mg/mL of said epothilone analog in a mixture of from about 50% to about 80% by volume tertiary-butanol in water.

5 (amended herein). The process of claim 3 wherein in step a) said epothilone analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.

6 (amended herein). The process of claim 4 wherein in step a) said epothilone analog is initially wetted with a mixture of from about 60% to about 95% by volume tertiary-butanol in water.

7 (canceled)

8 (amended herein). The process of claim 2 wherein said primary drying in step b) is carried out at a temperature of from about -25°C to -40°C and a pressure of from about 200 to 300 millitorr ~~for about 48 hours~~.

9 (canceled).

10 (amended herein). The process of claim 2 wherein said secondary drying in step c) is carried out at a temperature of from about 25°C to 30°C and a pressure of from about 150 to 300 millitorr ~~for about 48 hours~~.

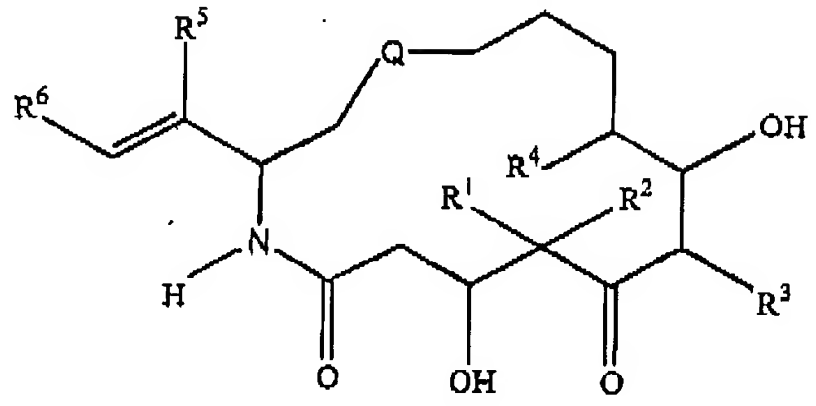
11 (amended herein). The process of claim ~~1~~ 30 wherein said surfactant is polyethoxylated castor oil.

12 (amended herein). The process of claim ~~2~~ 32 wherein said surfactant is polyethoxylated castor oil.

13 (amended herein). The process of claim 30 ~~4~~ wherein said second vial contains an amount of said mixture sufficient to form a solution of from about 2 mg/mL to about 4 mg/mL of said epothilone analog therein.

14 (canceled).

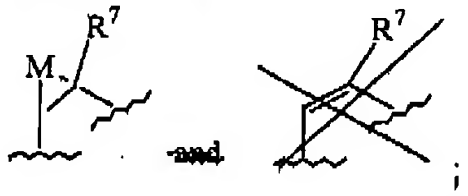
15 (amended herein). A pharmaceutical preparation comprising, in a first vial ~~separate vials~~, a lyophilized epothilone analog and in a second vial, a quantity of a suitable solvent or solvent mixture therefor such that when the contents of said first and second vials are combined, the lyophilized epothilone analog is reconstituted into a resulting solution ~~contains from about 2 mg/mL to about 4 mg/mL of said epothilone analog, said solvent comprising a mixture of about equal parts by volume of dehydrated ethanol and a suitable nonionic surfactant~~, said epothilone analog being represented by formula I:



I

wherein:

Q is ~~selected from the group consisting of~~



~~and~~ ;

M is ~~selected from the group consisting of~~ oxygen, ~~sulfur, NR^8, and CR^9R^{10}~~;

each R^1, R^2, R^3, R^4, R^5, and R^7, ~~R^{11}, R^{12}, R^{13}, R^{14}, and R^{15}~~ is, independently, selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R^1 and R^2 are alkyl, they can be joined to form cycloalkyl;

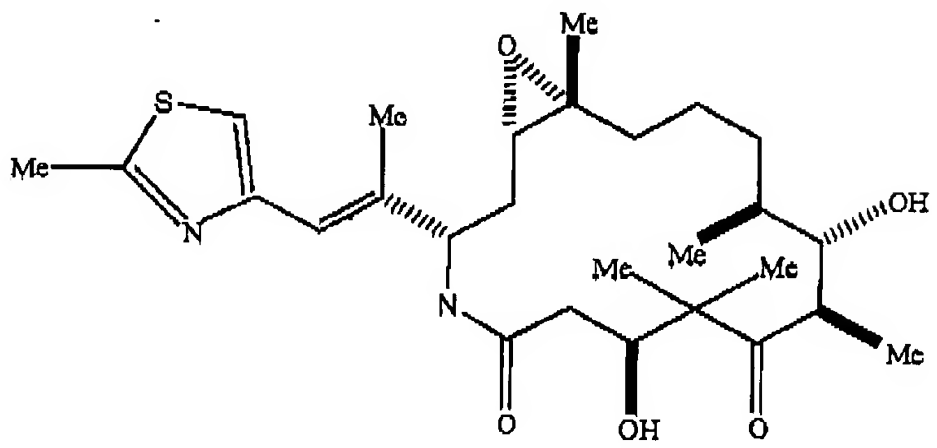
R^6 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocyclo and substituted heterocyclo;

~~R^8 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, $R^{11}C=O$, $R^{12}OC=O$ and $R^{13}SO_2$; and~~

~~each R^9 and R^{10} is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocycle, hydroxy, $R^{14}C=O$, and $R^{15}OC=O$;~~

and any salts, solvates, or hydrates thereof.

16 (original). The pharmaceutical preparation of claim 15 wherein said epothilone analog is represented by formula II:



II

17 (amended herein). The pharmaceutical preparation of claim 16 wherein said solvent or solvent mixture comprises a nonionic surfactant that is polyethoxylated castor oil.

18 (canceled).

19 (amended herein). A process for forming a pharmaceutical composition for parenteral administration comprising mixing the contents of the first and second vials of the pharmaceutical preparation of ~~any of~~ claim 16 to effect solution of said lyophilized epothilone analog and diluting the resultant solution with a quantity of a suitable parenteral diluent such that the concentration of said epothilone analog therein is ~~will be~~ from about 0.1 mg/mL to about 0.9 mg/mL.

20 (canceled).

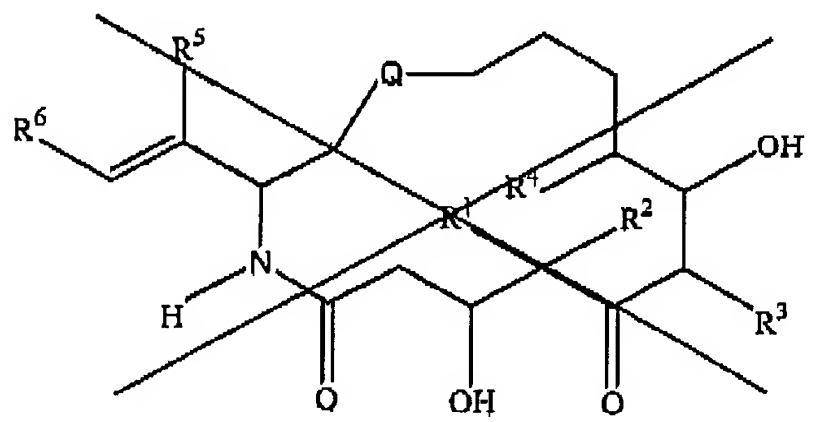
21 (canceled).

22 (original). The process of claim 19 wherein said diluent is Lactated Ringer's Injection.

23 (canceled).

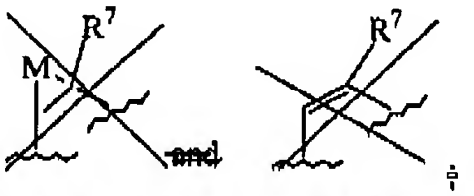
24 (canceled).

25 (amended herein). A process for treating a patient in need of treatment ~~with an epothilone analog represented formula I:~~



~~wherein:~~

~~Q is selected from the group consisting of~~



~~and~~

~~M is selected from the group consisting of oxygen, sulfur, NR^9, and CR^9R^{10};~~

~~each R^1, R^2, R^3, R^4, R^5, R^7, R^{11}, R^{12}, R^{13}, R^{14} and R^{15} is independently selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl and heterocyclo, and wherein R^1 and R^2 are alkyl, they can be joined to form a cycloalkyl;~~

~~R^6 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, aryl, substituted aryl, cycloalkyl, heterocycle and substituted heterocycle;~~

~~R^8 is selected from the group consisting of hydrogen, alkyl, substituted alkyl, $R^{11}C=O$, $R^{12}OC=O$ and $R^{13}SO_2$; and~~

~~each R^9 and R^{10} is, independently, selected from the group consisting of hydrogen, halogen, alkyl, substituted alkyl, aryl, heterocycle, hydroxy, $R^{14}C=O$, and $R^{15}OC=O$;~~

~~and any salts, solvates, or hydrates thereof,~~ comprising administering to said patient, by intravenous injection, an effective amount of a pharmaceutical composition of claim 19.

26 (canceled).

27 (canceled).

28.(original) The process of claim 25 wherein said diluent is Lactated Ringer's Injection.

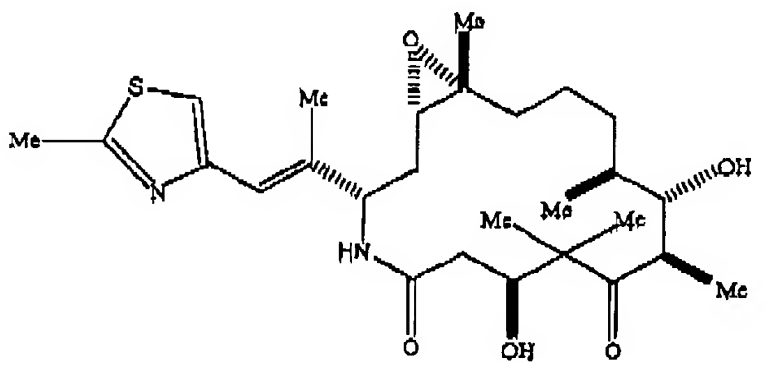
29. (canceled).

30 (New). The process of claim 1, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a mixture comprising at least one suitable nonionic surfactant and at least one dehydrated alcohol to effect reconstitution of the lyophilized product.

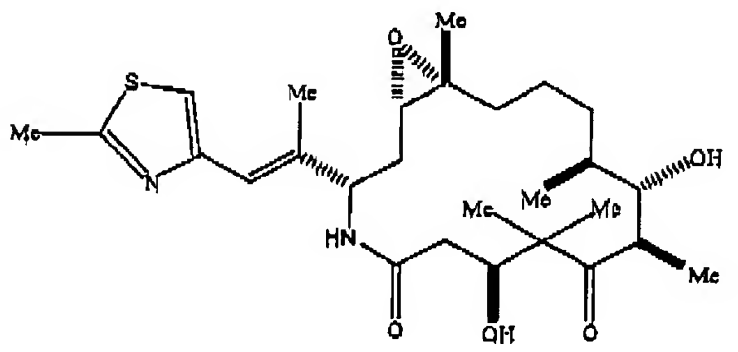
31 (New). The process of claim 30 wherein the mixture comprises about equal parts by volume of anhydrous ethanol and the at least one nonionic surfactant.

32 (New). The process of claim 30 wherein said epothilone analog is:



33 (New). The pharmaceutical preparation of claim 15, wherein said solvent is a mixture comprising about equal parts by volume of dehydrated ethanol and at least one suitable nonionic surfactant.

34 (New). A process for formulating, for parenteral administration, an epothilone analog having the formula:



comprising:

a) dissolving said epothilone analog in a mixture of tertiary butanol and water to form a solution, wherein the mixture comprises at least about 50% by volume tertiary butanol;

b) performing primary drying of said solution at a temperature, chamber pressure and period of time sufficient to form a primary lyophilized product; and

c) performing secondary drying of the primary lyophilized product at a temperature, chamber pressure and for a period of time sufficient to form a lyophilized product of the epothilone analog.

35 (New) The process of claim 34, wherein said step a) of dissolving said epothilone analog is carried out at a temperature below ambient temperature.

35 (New) The process of claim 34, wherein said step a) of dissolving said epothilone analog is carried out at a temperature in the range of from about 5°C to about 15°C.

36 (New). The process of claim 34, wherein said step a) of dissolving said epothilone analog comprises first, wetting said epothilone analog with a mixture of at least about 60% by volume tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains at least about 50% by volume tertiary-butanol in water.

37 (New). The process of claim 34, wherein said step a) of dissolving said epothilone is carried out in the absence of an excipient.

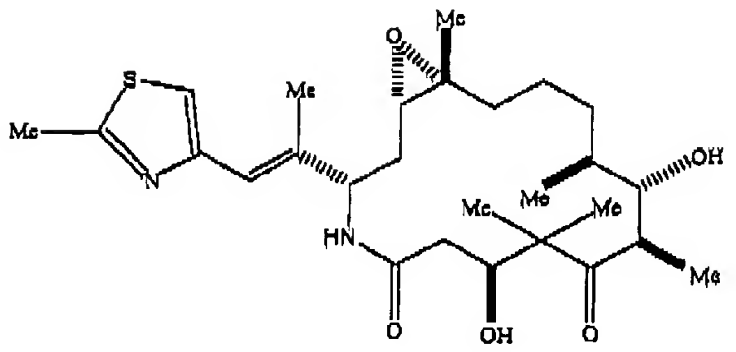
38 (New). The process of claim 34 wherein said primary drying in step b) is carried out at a temperature of from about -10°C to -40°C and at a chamber pressure of from about 50 to 300 millitorr for a period of up to about 96 hours.

39 (New). The process of claim 38 wherein said secondary drying in step c) is carried out at a temperature of from about 10°C to 30°C and at a chamber pressure of from about 150 to 300 millitorr for a period of up to about 96 hours.

40 (New). The process of claim 34, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a solvent mixture to effect reconstitution of the epothilone analog, wherein the solvent mixture of the second vial comprises at least one suitable nonionic surfactant and at least one anhydrous alcohol.

41 (New). A process for formulating, for parenteral administration, an epothilone analog represented by formula II:



comprising:

a) dissolving said epothilone analog to form a solution, comprising first, wetting said epothilone analog with a mixture of at least about 60% by volume tertiary-butanol in water, and then adding sufficient water, or a mixture of tertiary-butanol and water, so that the resulting solution contains at least about 50% by volume tertiary-butanol in water, wherein said step of dissolving is carried out at a temperature below ambient temperature;

b) performing primary drying of said solution at a temperature, chamber pressure and for a period of time sufficient to form a primary lyophilized product; and

c) performing secondary drying of the primary lyophilized product at temperature, chamber pressure and for a period of time sufficient to form a lyophilized product of the epothilone analog.

42 (New). The process of claim 41 wherein,

step b) of primary drying of said solution is performed at a temperature of about -10°C to about -40°C under vacuum of from about 50 millitorr to about 300 millitorr for from about 24 hours to about 96 hours; and

step c) of secondary drying is performed at a temperature of from about 10°C to about 30°C under vacuum of from about 50 millitorr to about 300 millitorr for from 24 hours to about 96 hours to provide a lyophilized product of the epothilone analog.

43 (New). The process of claim 42 wherein,

step a) of dissolving said epothilone analog is carried out at a temperature of from -5°C to about 15°C.

44 (New). The process of claim 43 wherein,

step a) of dissolving said epothilone analog is carried out in the absence of an excipient.

45 (New). The process of claim 43, further comprising the step of:

d) packaging said lyophilized product of the epothilone analog in a first vial and packaging in a second vial a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

46 (New) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 1.

47 (New) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 2.

48 (New) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 34.

49 (New) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 39.

50 (New) A pharmaceutical preparation comprising a lyophilized epothilone analog prepared according to claim 43.

51 (New) A pharmaceutical product comprising at least a first and a second vial wherein the first vial contains a lyophilized epothilone analog prepared according to claim 2, and the second vial contains a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

52 (New) A method of treating a patient comprising, mixing the contents of the first and second vials of the pharmaceutical product of claim 51 to provide an epothilone solution, diluting the epothilone solution with a quantitiy of a suitable parenteral diluent to prepare an intravenous formulation, and administering the intravenous formulation to the patient.

53 (New) A pharmaceutical product comprising at least a first and a second vial wherein the first vial contains a lyophilized epothilone analog prepared according to claim 34, and the second vial contains a sufficient quantity of a solution to effect reconstitution of the lyophilized epothilone analog, wherein the solution of the second vial comprises about equal amounts of at least one suitable nonionic surfactant and at least one anhydrous alcohol.

54 (New) A method of treating a patient comprising, mixing the contents of the first and second vials of the pharmaceutical product of claim 53 to provide an epothilone solution, diluting the epothilone solution with a quantitiy of a suitable parenteral diluent to prepare an intravenous formulation, and administering the intravenous formulation to the patient.